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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/17/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/623,596

Applicant(s)

WACHI ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 9 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action (Paper No. 9 mailed December 19, 2001), Applicants filed a response and amendment (Paper No. 11 received April 19, 2002). Said amendment cancelled Claim 4 and amended Claims 1-3 and 6-9 and added new Claim 10. Thus, Claims 1-3 and 5-10 are pending in the instant application and will be examined herein.

### ***Priority***

2. As previously noted, the request for the benefit of priority for the International Application No. PCT/JP99/01084 filed on March 5, 1999 and the foreign application Japan 10-55608 filed on March 6, 1998 as requested in the declaration, is noted.

### ***Drawings***

3. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

### ***Maintained - Objections to the Specification***

4. Previous objection to the Abstract for not completely describing the disclosed subject matter is maintained. No reference to the source species is included in the amended Abstract.

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***Withdrawn - Claim Objections***

5. Previous objection to Claims 1-4 for using the term "bacterium" is withdrawn by virtue of Applicants' amendment.

6. Previous objection to Claims 6-7 and 8-9 for reciting "in Sequence Listing" or "in Sequence" in the claims is withdrawn by virtue of Applicants' amendment deleting these phrases.

7. Previous objection to Claims 8-9 for the phrase "an activity for binding to penicillin", which does not define an activity is withdrawn by virtue of Applicants' amendment.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

8. Previous rejection of Claims 1-7 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrases "wherein penicillin binding protein (PBP) does not normally function" and "the PBP gene on chromosome" is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims. The amended claims 1-3 and 5-7 are still confusing but for different reasons; see new rejections below.

9. Previous rejection of Claims 2-4 under 35 U.S.C. § 112, second paragraph, as being indefinite for the reference to "**the** first temperature" and "**the** second temperature" (emphasis added) is withdrawn by virtue of Applicants' amendment to ---a first temperature---.

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10. Previous rejection of Claim 4 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “**the** penicillin binding protein” (emphasis added) is withdrawn by virtue of Applicant’s cancellation of said claim.

11. Previous rejection of Claim 8 under 35 U.S.C. § 112, second paragraph, as being indefinite for the claim wording in item (B) is unclear as to the limitation of “an activity for binding to penicillin” is withdrawn by virtue of Applicants’ amendment deleting this phrase.

12. Previous rejection of Claim 9 under 35 U.S.C. § 112, second paragraph, as being indefinite for the claim wording in item (b) is unclear as to the limitation of “codes for a protein having an activity for binding to penicillin” is withdrawn by virtue of Applicants’ amendment.

13. Previous rejection of Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “stringent condition” is withdrawn by virtue of Applicants’ amendment to Claim 9 introducing the hybridization conditions.

14. Previous rejection of Claim 4 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants’ cancellation of said claim.

15. Previous rejection of Claims 8 and 9 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants’ amendment adding functional claim language and specific structural language.

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16. Previous rejection of Claim 4 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' cancellation of said claim.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

17. Previous rejection of Claims 1-3 and 5-7 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants' argue that the instant claims, as amended, are drawn to a method using a coryneform having the function of a PBP protein being reduced or eliminated and this has adequate written description by virtue of the disclosed PBP gene disruption in coryneform. Firstly, the single example is not adequate written description of this claimed genus. Having the single, disclosed species, one of skill in the art would be unable to predict the structure of the other members of the genus necessary to practice the claimed invention. Secondly, the method claims, as amended, are much broader, including a coryneform wherein all PBPs are deleted (see 112, second paragraph rejection below). No examples of this genus are provided. Thus, the instant rejection is maintained.

18. Previous rejection of Claims 1-3 and 5-7 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the disclosure on pages 11, 12, 16, and 17 enable the instant claims. As previously noted, because the specification is enabling for methods using coryneform whose PBP3 gene (60 kD species) is deleted (see specification Example 4) and a plasmid containing a PBP gene, but the specification does not reasonably provide enablement for methods using coryneform whose entire PBP function is deleted.

Previously omitted Claim 3 has now been included in the instant rejection by virtue of Applicants' amendment to Claim 3. The PBP gene on the chromosome is unclear (see 112, second paragraph rejection below).

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

19. Previous rejection of Claims 8-9 under 35 U.S.C. § 102(b) as being anticipated by Cole *et al.* (GenBank Accession Number Z95388 "Mycobacterium tuberculosis H37Rv complete genome, segment 96/162" created May 14, 1997) as evidenced by Cole *et al.* (GenBank Accession Number B70886 "probably penicillin binding protein - Mycobacterium tuberculosis (strain H37RV)" created July 17, 1998) is withdrawn by virtue of Applicants' amendment adding particular structural limitations into Claims 8 and 9 which are not met by Cole *et al.*

**NEW OBJECTIONS/REJECTIONS**

***Claim Objections***

20. Claim 10 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation of "not less than 50% homologous" is certainly met by the parent Claim 9, according to its hybridization conditions. Thus, the limitation of Claim 10 does not further limit Claim 10.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, lines 3-4, the phrase “wherein **a** penicillin binding protein is not produced” (emphasis added) means that no PBP can be found in the cell. In view of the specification, this does not seem to be Applicants’ intended meaning. In Claim 1, line 5 referring to the reduced/eliminated option, the antecedent basis of “**said produced** penicillin binding protein” (emphasis added) is unclear since previously in the claim, *no* PBP is produced. Additionally, it is unclear if the mutated (reduced/eliminated) PBP is endogenous or exogenous, and it is unclear if “**the function**” (emphasis added) is the penicillin binding activity or some other activity carried out by PBPs.

In Claim 3, the phrase “**said PBP gene** on the bacterial chromosome” (emphasis added) does not have proper antecedent basis since the reference to any gene in the claims is limited to the plasmid-borne gene.

In Claims 5 and 6, the phrase defining “**the penicillin binding protein**” (emphasis added) does not clarify Claim 1 because Claim 1 is drawn to more than one PBP not being produced (see above discussion of no PBP being found in the cell). This phrase is clear with respect to the reduced or eliminated PBP of Claim 1.

In Claim 7, the phrase defining “**the PBP gene**” (emphasis added) is unclear in antecedent basis to the plasmid-borne gene of the chromosomal gene.



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The instant claims are seem to be drawn to method of producing glutamate using coryneform wherein said coryneform have reduced (or eliminated) PBP activity due to deletion or mutation of a PBP gene. As written; however, the claim is drawn to coryneform having no PBPs or having all mutated PBPs. Appropriate clarification and/or correction are required.

***Summary of Pending Issues***

22. The following is a summary of the issues pending in the instant application:

- a) The benefit of priority to the foreign application Japan 10-55608 filed on March 6, 1998 cannot be granted without a certified translation of the document. Priority to the international application has been granted.
- b) The Abstract stands objected to for not completely describing the disclosed subject matter.
- c) Claim 10 stands objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
- d) Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 112, second paragraph, for being confusing.
- e) Claims 1-3 and 5-7 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- f) Claims 1-3 and 5-7 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

***Allowable Subject Matter***

23. Claims 8 and 9 are considered free of the prior art. The closest prior art was noted in the previous Office action as Cole *et al.* teaching a *M. tuberculosis* gene encoding a "probably

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penicillin binding protein". The structural similarities between the *M. tuberculosis* gene and SEQ ID NO:1 are outside the metes and bounds of Claims 8 and 9.

### *Conclusion*

24. Claims 8 and 9 are allowed. Claim 10 is objected to. Claims 1-3 and 5-7 are rejected for the reasons cited above. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky".

ELIZABETH SLOBODYANSKY, PH.D  
PRIMARY EXAMINER

KMK  
June 12, 2002